

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0988305	(X3) Date Survey Completed 10/09/2018
Name of Provider or Supplier Marina Diagnostic Lab Llp	Street Address, City, State 1616 Voorhies Avenue, Suite A, Brooklyn, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT reports and PT records from the American Proficiency Institute (API) PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the specialty Endocrinology and the test analytes Cortisol, Serum Human Chorionic Gonadotropin (HCG), Thyroid Stimulating Hormone (TSH). The following scores were assigned: Endocrinology 2018 second event = 72% 2018 third event = 0% [failure to participate] Cortisol 2018 second event = 0% 2018 third event = 0% [failure to participate] Serum HCG 2018 first event = 40% 2018 second event = 100% 2018 third event = 0% [failure to</p>

participate] TSH 2018 second event = 60% 2018 third event = 0% [failure to participate] This is considered unsuccessful PT performance. Refer to D2107 and D2108.

D2089

ROUTINE CHEMISTRY
CFR(s): 493.841(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the specialty Chemistry and twenty five chemistry test analytes. The following scores were assigned: 2018 third event = 0% [failure to participate] This is considered unsatisfactory PT performance.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analytes Cortisol, Serum HCG and TSH. The following scores were assigned: Cortisol 2018 second event = 0% 2018 third event = 0% [failure to participate] Serum HCG 2018 first event = 40% 2018 second event = 100% 2018 third event = 0% [failure to participate] TSH 2018 second event = 60% 2018 third event = 0% [failure to participate] This is considered unsuccessful PT performance.

D2108

ENDOCRINOLOGY
CFR(s): 493.843(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a PT desk review of the CMS PT reports and PT records from the API PT

	<p>program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the specialty Endocrinology. The following scores were assigned: 2018 second event = 72% 2018 third event = 0% [failure to participate]</p>
<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a PT desk review of the CMS PT reports and PT records from the API PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the Cell Identification (ID)/White Blood Cell differential (WBC Diff). The following scores were assigned: 2018 first event = 67% This considered an unsatisfactory PT performance.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on PT desk review of the CMS PT and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the specialty Endocrinology and the test analytes Cortisol, Serum HCG, TSH, and the specialty Chemistry and twenty five chemistry test analytes and the test analyte Cell ID/WBC Diff. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the specialty Endocrinology and the test analytes Cortisol, Serum HCG, TSH, and the specialty Chemistry and twenty five chemistry test analytes. Endocrinology 2018 second event = 72% 2018 third event = 0% [failure</p>

to participate] Cortisol 2018 second event = 0% 2018 third event = 0% [failure to participate] Serum HCG 2018 first event = 40% 2018 second event = 100% 2018 third event = 0% [failure to participate] TSH 2018 second event = 60% 2018 third event = 0% [failure to participate] This is considered unsuccessful PT performance. Chemistry and twenty five chemistry test analytes. 2018 third event = 0% [failure to participate] Cell Identification /WBC Diff 2018 first event = 67% This is considered unsatisfactory PT performance.